FEB 1 7 2006

510(k) Summary

CIV-ob Obstetrical Monitoring Software Application

510(k) Number K_____

Submitter's Name:

CIVNET Communication Ltd.
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Rudi Lokits
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Trade Name:

CIV-ob Obstetrical Monitoring Software Application

Classification Name:

System, Monitoring, Perinatal

Classification:

The FDA has classified these devices as a class II device (product code HGM) and are reviewed by the Obstetrics and Gynecology Devices Group.

Predicate Devices:

The CIV-ob Obstetrical Monitoring Software Application is substantially equivalent to:

- GE Marquette Medical Quantitative Sentinel System, cleared under K993008, Dec 6, 1999.

- ClinComp. Intl CIS w/ FMRD, cleared under K931133.

Performance Standards:

No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug, and Cosmetic Act. However, to the best of our knowledge, the CIV-ob Obstetrical Monitoring Software Application complies with the following voluntary standard:

- IEC 60601-1-4 Computer Controlled Medical Devices

Acceptance Criteria and Risk Analysis:

Acceptance criteria for compliance with the standards is detailed in CIVnet's IEC 60601-1-4 report and Risk Analysis.

The software risks addressed are communication, loss of power conditions, out of limit conditions, server communication, installation, memory capacity.
These are checked as part of CIVnet's Software Test Procedure for validation of the software.

The hardware risks are those associated with the off-the-shelf devices and their possible failure.

The User Interface risks addressed are Patient Data Security and accuracy.

Device Description and Intended Use:

The CIVNET CIV-ob is a software application that is intended for use as a clinical data management system (also referred to as a clinical information system – CIS). The function of the system is the management of fetal and maternal vital heart rate and uterine vital signs clinical data automatically acquired from a bedside fetal monitor, for the purpose of providing, ready and organized access to patient and/or clinical data that would normally be provided on paper records and/or separate clinical systems/devices. The CIV-ob serves as an electronic medical record. The CIV-ob operates with off-the-shelf software and hardware. The device is intended for use in a hospital/clinical environment.

Substantial Equivalence:

The CIV-ob Obstetrical Monitoring Software Application is substantially equivalent to its predicate devices:

- GE Marquette Medical Quantitative Sentinel System, cleared under K993008, Dec 6, 1999.

- ClinComp. Intl CIS w/ FMRD, cleared under K931133.

without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2006

Mr. Rudi Lokits
General Manager
CIVNET Communication Ltd.
Meshk 58, Ben Natan
Moshav Hemed, 50295
ISRAEL

Re: K051175
Trade/Device Name: CIV-ob Monitoring Software Application
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: December 29, 2005
Received: January 4, 2006

Dear Mr. Lokits:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K051175

Device Name: CIV-ob Monitoring Software Application

Indications for Use:

The CIVNET CIV-ob software application is intended for automatic fetal monitor patient data management. The application does this by:

a) Displaying on-line fetal heart rate and TOCO data received from the patient bed-side in a one-to-one representation as it is displayed on the fetal monitor paper printout.
b) Providing the means to control and display multiple beds simultaneously.
c) Providing automatic Archiving of the data.
d) Provide the ability to interface with different fetal monitors operating with the same interface protocol.
e) Easy interfacing with any IT patient record system for data acquisition, viewing and storage of electronic patient record.
f) Provide visual notification of when acquired fetal monitor heart rate exceed the user defined limits for high and low fetal heart rate and poor signal quality.
g) Providing the ability to record, with patient record, fluid input and output information that is defined by the user.
h) Providing the ability to archive files to a secondary or tertiary storage medium (i.e. optical disk).
i) Providing the ability to print (locally or remote) patient records.
j) Providing the ability to review fetal monitor data remotely over the TCP/IP

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of Obstetrics and Gynecology Devices

510(k) Number _____

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

PREMARKET NOTIFICATION

David A Agnew

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051175